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IFW 1614



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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: BRÖGMANN, Bianca *et al.*

Confirmation No.: 1884

Serial No.: 10/510,674

Art Unit: 1614

Filing Date: May 23, 2005

Examiner: To Be Assigned

Title: PHARMACEUTICAL  
PREPARATION CONTAINING  
OXYCODONE AND NALOXONE

Attorney Docket No: 6750-308-999  
CAM No.: 305158-999301

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:

1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.

1b. A legible copy of :

☒ Each publication or that portion which caused it to be listed on the PTO-1449;

☐ For each cited pending unpublished U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion that have been checked to be unavailable at the USPTO's private PAIR system;

☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report;

☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications;

☐ All other information or portion which caused it to be listed on the PTO-1449.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.J./

- 1c. ☐ Pursuant to 37 C.F.R. §1.98(a)(2)(ii), copies of the cited U.S. patents and U.S. patent application publications are not submitted herewith unless required by the office.
- 1d. ☐ Pursuant to 1287 OG 163, copies of cited pending unpublished applications that are available at the USPTO's private PAIR system are not submitted herewith.
2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):
- ☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
  - ☒ Before the mailing of the first Office action on the merits;
  - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

*(Check either Item 3a or 3b)*

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed.
  - ☐ to be charged to Jones Day Deposit Account No. 50-3013.

*(Item 3b to be checked if any reference known for more than 3 months)*

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The Certification Statement in Item 5 below is applicable.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

- ☐ enclosed.
  - ☐ to be charged to Jones Day Deposit Account No. 50-3013.
5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked):

*(Check either Item 5a or 5b)*

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- 5c. ☐ Pursuant to 37 C.F.R. §1.704(d), each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
6. ☐ This application is a continuation application under 37 C.F.R. §1.53(b) or (d).  
*(Check appropriate Items 6a, 6b and/or 6c)*
- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.
- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior application Serial No. \_\_\_\_\_, filed on \_\_\_\_\_, of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. \_\_\_\_\_, filed on \_\_\_\_\_, and are provided herewith.
7. ☒ This is a Supplemental Information Disclosure Statement. (Check Item 7a)
- 7a. ☒ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on March 2, 2006.
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:  
*( Check Item 8a, 8b, or 8c)*
- 8a. ☐ Satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ Set forth in the application.
- 8c. ☐ Enclosed as an attachment hereto.

9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Jones Day Deposit Account No. 50-3013.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability and no representation is made that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

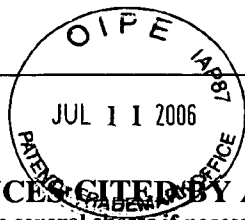
Respectfully submitted,

Date: July 11, 2006

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**LIST OF REFERENCES CITED BY APPLICANT**  
(Use several sheets if necessary)

<b>ATTY. DOCKET NO.</b> 6750-308-999	<b>APPLICATION NO.</b> 10/510,674
<b>APPLICANT</b> Brogmann <i>et al.</i>	
<b>FILING DATE</b> May 23, 2005	<b>ART UNIT</b> 1614

**U.S. PATENT DOCUMENTS**

*Examiner Initials	Document Number	Date mm/dd/yy	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

**FOREIGN PATENT DOCUMENTS**

*Examiner Initials	Foreign Patent Document Country Code, Number, Kind Code (if known)	Date mm/dd/yy	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
	B08 WO 03/024430 A1	03/27/03	EGALET A/S		
	B09 WO 03/024429 A1	03/27/03	EGALET A/S		

**NON PATENT LITERATURE DOCUMENTS**

*Examiner Initials	Include name of the author (in CAPITAL LETTERS), (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T

**EXAMINER** /Samira Jean-louis/  
NYJD-1629633v1

**DATE CONSIDERED** 07/15/2008

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.J./